K 102405

BARD
ACCESS SYSTEMS

510(k) Summary
21 CFR 807.92(a)

JUL 2 1 2011

Extension Set for Bard® Proximally Valved Catheters

General Provisions	Submitter Name: Address: Contact Person: Telephone Number: Fax Number: Date of Preparation:	Bard Access Systems, Inc. 605 North 5600 West Salt Lake City, UT 84116 Lynn Kirchoff Regulatory Affairs Manager (801) 522-5636 (801) 522-5425 March 9, 2011
Subject Device	Trade Name: Classification Name:	**Extension Set** for Bard Proximally Valved Catheters Set, Administration, Intravascular FPA, 21 CFR § 880.5440 Class II
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	**IV Extension Set** with Needleless Access Device Set, Administration, Intravascular FPA, 21 CFR § 880.5440 Class II K980992 Venetec Intl., Inc. now owned by Bard Medical Division
Device Description	The Extension Set is designed for Bard proximally valved catheters and attaches to the end of the catheter hub for use in the administration of fluids. The Extension Set opens the valve to facilitate central venous pressure monitoring and/or blood sampling. Extension Sets are packaged individually for single use for a period no longer than 96 hours.	
Intended Use	An extension set to be used as an extension to the intravascular administration set used for fluid delivery through Bard proximally valved catheters. The extension set will connect the IV administration set to the catheter.	
Indications For Use	An extension set to be used as an extension to the intravascular administration set used for fluid delivery through Bard proximally valved catheters. The extension set will connect the IV administration set to the catheter.	

Technological Characteristics	Technological characteristics of the subject Bard Extension Set are equivalent with respect to the basic design and function to those of the predicate IV Extension Set with Needleless Access Device. Both the subject and predicate device have infusion tubing with ISO compatible luers connections with the exception that the subject device has a cannula on the distal end of the device. Differences do not raise any new questions regarding safety and effectiveness. Accepted scientific methods such as, performance (bench) testing do exist for assessing the effect of the differences in characteristics.
Summary of Nonclincal Testing	The Bard Extension Set met the bench performance testing requirements of the following standards where applicable in conjunction with in-house protocols which were used to determine appropriate methods for evaluating the performance of the device: ▪ ISO 8536-4:2007 :- Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed ▪ ISO 594-1:1986 :- Conical Fittings with a 6 % (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment - Part 1: General Requirements ▪ ISO 594-2:1998 :- Conical Fittings with a 6 % (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment - Part 2: Lock Fittings ▪ Guidance for Industry and FDA Review Staff - Intravascular Administration Sets Premarket Notification Submissions [510(k)], dated April 15, 2005 Risk management, including a failure modes and effects analysis (FMEA), of the subject device was conducted in accordance with ISO 14971:2009, Medical Devices – Risk Management for Medical Devices. No new types of safety or efficacy questions were identified for the subject Bard Extension Set. Biocompatibility assessment was conducted on the Bard Extension Set based on the guidelines presented in blue book memorandum #G95-1 entitled "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing and ISO 10993-1:2009 - Biological Evaluation of Medical Devices Part-1: Evaluation and Testing. The sterility of the Bard Extension Set is assured by using a validated sterilization method qualified in accordance with ISO 11135-1:2007 :- Sterilization of Healthcare products – Ethylene Oxide- Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices to a sterility assurance level (SAL) of 10^{-6}. Ethylene Oxide residual levels resulting from EtO Sterilization are in compliance with ISO 10993-7:2008 - Biological Evaluation of Medical Devices- Part 7: Ethylene Oxide Sterilization Residuals. The Bard Extension is also tested for pyrogenicity.

Summary of Verification Activities

Summary Results of Verification Testing	
Evaluation	**Predetermined Acceptance Criteria**
Assembly Leak	No leaks at 43.5 psi minimum (air method used)
Gravity Flow	750 ml/hr minimum
Priming Volume	NA, test and report results
Assembly Tensile	Must withstand an axial, static tensile force of 15 N (3.37 lbs) for 15 seconds
ISO 594 -1 & 2 Luer Testing	Must pass acceptance criteria outlined in ISO 594-1 and -2.
Aspiration Flow	NA, test and report results

Summary of Substantial Equivalence

Based on the indications for use, technological characteristics, and safety and performance testing, the subject **Bard Extension Set** met the requirements for its intended use/indications for use and is substantially equivalent in design, materials, sterilization, principles of operation and indications for use to current commercially available predicate infusion set.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Ms. Lynn M. Kirchoff
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C.R. Bard, Incorporated
605 North 5600 West
Salt Lake City, Utah 84116

JUL 21 2011

Re: K102405
Trade/Device Name: Extension Set for Bard Proximally Valved Catheters
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: June 27, 2011
Received: June 29, 2011

Dear Ms. Kirchoff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102405

Device Name: **Extension Set for Bard® Proximally Valved Catheters**

Indications for Use:

An extension set to be used as an extension to the intravascular administration set used for fluid delivery through Bard® proximally valved catheters. The extension set will connect the IV administration set to the catheter.

Prescription Use ✓ (Part 21 CFR §801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR §801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 7/21/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K102405